

## REMARKS

The Office Action dated September 24, 2002 has been carefully reviewed. Claims 1-55 are pending in this patent application. By this amendment, claims 1, 10-13, 17, 28, 45-48, 50 and 52-54 have been amended and claim 56 has been added. Reconsideration of this application, as amended, is respectfully requested.

### Examiner's Comments Regarding the Specification, Abstract and Drawings

The specification and abstract have been amended to correct a number of minor typographical errors, keeping in mind the comments offered by the Examiner.

### 35 U.S.C. § 112, Second Paragraph Rejections

Responsive to the rejection of claims 1-27, 45-48, 50, 52-54 under 35 U.S.C. § 112, second paragraph, Applicants have amended claims 1, 10-13, 17, 45-48, 50 and 52-54, keeping in mind the comments offered by the Examiner. Applicants respectfully submit that claims 1-27, 45-48, 50, 52-54 are now in allowable form.

### 35 U.S.C. § 102 Rejections

Claims 45-48 and 53-54 were rejected under 35 U.S.C. § 102(e) as being anticipated by Farey (U.S. Patent No. 6,203,575). Reconsideration of claims 45-48 and 53-54 is respectfully requested.

#### Claim 45

Claim 45 recites in part the following:

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

securing a final head portion to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

#### Farey Does Not Disclose the Invention of Claim 45

The mounting apparatus 1 of Farey does not include a scale mechanism having a value thereon. Rather, as seen in Figs. 12-14, the mounting apparatus 1 includes a floating disk D supporting a rotating disk with a mark H. The mark H is not a value. That is, the mark H is not a measurement of a degree of offset of a trial head. The mark H is merely an arbitrary mark which can be rotated to a marking on the test prosthesis head 8. After the test prosthesis has been removed from the mounting apparatus 1, another head 4 can be placed in the mounting apparatus and rotated to the spot marked by the H. In contrast, the impaction stand 70 of the present invention includes a scale having values 1-11,

as seen in Figs. 15, 16 and 18 of the present specification. Thus, Farey does not disclose or suggest Applicants' invention of claim 45.

The invention of claim 45 includes distinct advantages over Farey. By the trial offset indicia aligning with a value, the degree of offset can be quantified and recorded for future reference. In Fig. 18, for instance, the offset of the head can be quantified as "5" and recorded for future reference.

For all of the foregoing reasons, Farey does not disclose the subject matter of claim 45. Thus, claim 45 is allowable over Farey.

#### Discussion Re: Patentability of Claim 46

Claim 46 depends directly from claim 45. As a result, claim 46 is allowable for the reasons hereinbefore discussed with regard to claim 45. Moreover, claim 46 recites further novel and nonobvious limitations. Thus, claim 46 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 47

Claim 47 recites in part the following:

positioning said trial assembly in a scale mechanism . . . whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

attaching a final head portion in fixed relation to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

Thus, claim 47 recites subject matter substantially similar to the subject matter of claim 45. As a result, claim 47 is allowable for the reasons hereinbefore discussed with regard to claim 45. Moreover, claim 47 recites further novel and nonobvious limitations. Thus, claim 47 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 48

Claim 48 depends directly from claim 47. As a result, claim 48 is allowable for the reasons hereinbefore discussed with regard to claim 47. Moreover, claim 48 recites further novel and nonobvious limitations. Thus, claim 48 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 53

Claim 53 recites in part the following:

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

securing a final head portion to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

Thus, claim 53 recites subject matter substantially similar to the subject matter of claim 45. As a result, claim 53 is allowable for the reasons hereinbefore discussed with regard to claim 45. Moreover, claim 53 recites

further novel and nonobvious limitations. Thus, claim 53 is further allowable over the cited art.

Discussion Re: Patentability of Claim 54

Claim 54 recites in part the following:

positioning said trial assembly in a scale mechanism . . . whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

attaching a final head portion in fixed relation to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

Thus, claim 54 recites subject matter substantially similar to the subject matter of claim 45. As a result, claim 54 is allowable for the reasons hereinbefore discussed with regard to claim 45. Moreover, claim 54 recites further novel and nonobvious limitations. Thus, claim 54 is further allowable over the cited art.

Claims 28, 31-33, 35-37, 40-42, 44, 49-52 and 55 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kummer et al. (U.S. Patent No. 5,910,171). Reconsideration of claims 28, 31-33, 35-37, 40-42, 44, 49-52 and 55 is respectfully requested.

## Claim 28

Claim 28 recites in part the following:

a trial assembly including a trial body portion . . . , and a trial head portion having (i) a trial head member which includes a trial offset indicia, . . . ; and

a final prosthesis assembly including a final body portion . . . , and a final head portion having (i) a final head member which includes a final offset indicia.

(Emphasis added).

## Kummer Does Not Disclose the Invention of Claim 28

Kummer is completely silent as to the presence of a trial assembly.

Kummer only discloses a humeral component that is to be permanently implanted into a patient. Kummer makes no mention of the use of a trial humeral component. Thus, Kummer does not disclose or suggest both a trial assembly and a final prosthesis assembly, as recited by claim 28.

Kummer also does not disclose or suggest a head member which includes an offset indicia. The pin 50 and the pin securing hole 54 are disposed on the flat underside of the head 33 and thus are not visible when the head 33 is coupled to the stem 11. Because the pin 50 and the pin securing hole 54 are not visible, they are not capable of indicating a degree of offset of the head 33 to a user. That is, the pin 50 and the pin securing hole 54 are not indicia that indicate a degree of offset to a user. Thus, Kummer does not disclose or suggest a head member which includes an offset indicia, as recited by claim 28.

For all of the foregoing reasons, Kummer does not disclose the subject matter of claim 28. Thus, claim 28 is allowable over Kummer.

### Claim 31

Claim 31 recites in part the following:

said trial body portion includes a set of internal threads located within said trial bore,  
said trial head portion further includes an externally threaded fastener positioned within a passageway which extends through said trial head portion.

(Emphasis added).

### Kummer Does Not Disclose the Invention of Claim 31

The flutings of the bore 27 and of the shaft 41 of Kummer are not threads. The flutings of Kummer are characterized by being parallel to the axis of the shaft 41. The threads of the fastener of the present invention, in contrast, are characterized by being substantially perpendicular to the axis of the fastener, as can be seen in Figs. 8-11. Thus, Kummer does not disclose or suggest either a trial body portion including a set of internal threads, or a trial head portion including an externally threaded fastener, as recited by claim 31.

Kummer also does not disclose or suggest a passageway which extends through a trial head portion. The shaft receiving bore 51 does not extend through the head 33. That is, the bore 51 does not extend through from one side of the head 33 to another side of the head 33. Thus, Kummer does not disclose or suggest a fastener positioned within a passageway which extends through a trial head portion, as recited by claim 31.

For all of the foregoing reasons, Kummer does not disclose the subject matter of claim 31. Thus, claim 31 is allowable over Kummer.

#### Discussion Re: Patentability of Claims 32-33 and 35

Claims 32-33 and 35 depend directly from claim 28. As a result, claims 32-33 and 35 are allowable for the reasons hereinbefore discussed with regard to claim 28. Moreover, claims 32-33 and 35 recite further novel and nonobvious limitations. Thus, claims 32-33 and 35 are further allowable over the cited art.

#### Discussion Re: Patentability of Claim 36

Claim 36 recites in part the following:

a trial assembly including (i) a trial body portion, (ii) a trial head portion which includes a trial offset indicia, . . . ; and  
a final prosthesis assembly including a final body portion . . . ,  
and a final head portion having (i) a final head member which  
includes a final offset indicia.

(Emphasis added).

Thus, claim 36 recites subject matter substantially similar to the subject matter of claim 28. As a result, claim 36 is allowable for the reasons hereinbefore discussed with regard to claim 28. Moreover, claim 36 recites further novel and nonobvious limitations. Thus, claim 36 is further allowable over the cited art.

#### Discussion Re: Patentability of Claims 37, 41-42 and 44

Claims 37, 41-42 and 44 depend directly or indirectly from claim 36. As a result, claims 37, 41-42 and 44 are allowable for the reasons hereinbefore discussed with regard to claim 36. Moreover, claims 37, 41-42 and 44 recite



further novel and nonobvious limitations. Thus, claims 37, 41-42 and 44 are further allowable over the cited art.

#### Discussion Re: Patentability of Claim 40

Claim 40 recites in part the following:

said trial body portion includes a set of internal threads located within said trial bore,  
said fastener includes an externally threaded portion,  
said fastener is configured to be received within a passageway which extends through said trial head portion.

(Emphasis added).

Thus, claim 40 recites subject matter substantially similar to the subject matter of claim 31. As a result, claim 40 is allowable for the reasons hereinbefore discussed with regard to claim 31. Moreover, claim 40 recites further novel and nonobvious limitations. Thus, claim 40 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 49

Claim 49 recites in part the following:

a trial assembly including a trial body portion . . . , and a trial head portion having (i) a trial head member which includes a trial offset indicia, . . . ; and  
a final prosthesis assembly including a final body portion . . . , and a final head portion having (i) a final head member which includes a final offset indicia.

(Emphasis added).

Thus, claim 49 recites subject matter substantially similar to the subject matter of claim 28. As a result, claim 49 is allowable for the reasons hereinbefore discussed with regard to claim 28. Moreover, claim 49 recites further novel and nonobvious limitations. Thus, claim 49 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 50

Claim 50 depends directly from claim 49. As a result, claim 50 is allowable for the reasons hereinbefore discussed with regard to claim 49. Moreover, claim 50 recites further novel and nonobvious limitations. Thus, claim 50 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 51

Claim 51 recites in part the following:

a trial assembly including (i) a trial body portion, (ii) a trial head portion which includes a trial offset indicia, . . . ; and  
a final prosthesis assembly including a final body portion . . . ,  
and a final head portion having (i) a final head member which includes a final offset indicia.

(Emphasis added).

Thus, claim 51 recites subject matter substantially similar to the subject matter of claim 28. As a result, claim 51 is allowable for the reasons hereinbefore discussed with regard to claim 28. Moreover, claim 51 recites

further novel and nonobvious limitations. Thus, claim 51 is further allowable over the cited art.

Discussion Re: Patentability of Claim 52

Claim 52 depends directly from claim 51. As a result, claim 52 is allowable for the reasons hereinbefore discussed with regard to claim 51. Moreover, claim 52 recites further novel and nonobvious limitations. Thus, claim 52 is further allowable over the cited art.

Discussion Re: Patentability of Claim 55

Claim 55 recites in part the following:

a trial assembly including a trial body portion . . . , and a trial head portion having (i) a trial head member which includes a trial offset indicia, . . . ; and

a final prosthesis assembly including a final body portion . . . , and a final head portion having (i) a final head member which includes a final offset indicia.

(Emphasis added).

Thus, claim 55 recites subject matter substantially similar to the subject matter of claim 28. As a result, claim 55 is allowable for the reasons hereinbefore discussed with regard to claim 28. Moreover, claim 55 recites further novel and nonobvious limitations. Thus, claim 55 is further allowable over the cited art.

Claims 49-55 were rejected under 35 U.S.C. § 102(e) as being anticipated by Huebner et al. (U.S. Patent No. 6,102,953). Reconsideration of claims 49-55 is respectfully requested.

#### Claim 49

Claim 49 recites in part the following:

a trial assembly including a trial body portion . . . , and a trial head portion having (i) a trial head member which includes a trial offset indicia, . . . ; and

a final prosthesis assembly including a final body portion . . . , and a final head portion having (i) a final head member which includes a final offset indicia.

(Emphasis added).

#### Huebner Does Not Disclose the Invention of Claim 49

Huebner does not disclose or suggest a head member which includes an offset indicia. The recess 108 is not an offset indicia because the associated head 12 is not offset. That is, Huebner is completely silent as to the head 12 being offset in any way.

Moreover, the recess 108 is disposed on the flat underside of the head 12 and thus is not visible when the head 12 is coupled to the body 18, as best seen in Fig. 17. In contrast, an indicia 44 of the present invention is quite visible, as best seen in Fig. 18. Because the recess 108 of Huebner is not visible, it would not be capable of indicating to a user a degree of offset of the head 12 even if there were such an offset. That is, the recess 108 is not an indicia that indicates a degree of offset to a user.

Similarly, the tapered bore 226 of Huebner is disposed on the flat underside of the head 212 and thus is not visible when the head 212 is coupled to the body 218, as is made evident by Fig. 25. Because the bore 226 is not visible, it would not be capable of indicating a degree of offset of the head 212 to

a user. That is, the bore 226 is not an indicia that indicates a degree of offset to a user. Thus, Huebner does not disclose or suggest a head member which includes an offset indicia, as recited by claim 49.

For all of the foregoing reasons, Huebner does not disclose the subject matter of claim 49. Thus, claim 49 is allowable over Huebner.

#### Discussion Re: Patentability of Claim 50

Claim 50 depends directly from claim 49. As a result, claim 50 is allowable for the reasons hereinbefore discussed with regard to claim 49. Moreover, claim 50 recites further novel and nonobvious limitations. Thus, claim 50 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 51

Claim 51 recites in part the following:

a trial assembly including (i) a trial body portion, (ii) a trial head portion which includes a trial offset indicia, . . . ; and  
a final prosthesis assembly including a final body portion . . . ,  
and a final head portion having (i) a final head member which includes a final offset indicia.

(Emphasis added).

Thus, claim 51 recites subject matter substantially similar to the subject matter of claim 49. As a result, claim 51 is allowable for the reasons hereinbefore discussed with regard to claim 49. Moreover, claim 51 recites

further novel and nonobvious limitations. Thus, claim 51 is further allowable over the cited art.

#### Discussion Re: Patentability of Claim 52

Claim 52 depends directly from claim 51. As a result, claim 52 is allowable for the reasons hereinbefore discussed with regard to claim 51. Moreover, claim 52 recites further novel and nonobvious limitations. Thus, claim 52 is further allowable over the cited art.

#### Claim 53

Claim 53 recites in part the following:

a trial head portion having (i) a trial head member which includes a trial offset indicia.

(Emphasis added).

Thus, claim 53 recites subject matter substantially similar to the subject matter of claim 49. As a result, claim 53 is allowable for the reasons hereinbefore discussed with regard to claim 49.

Moreover, claim 53 recites in part the following:

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism.

(Emphasis added).

#### Huebner Does Not Disclose the Invention of Claim 53

Huebner does not disclose or suggest positioning a trial assembly in a scale mechanism whereby a trial offset indicia of a trial head portion aligns with a value on the scale mechanism, as recited by claim 53. Firstly, as discussed above, Huebner does not disclose a trial head portion having a trial offset indicia. Secondly, Huebner does not disclose such a scale mechanism. More specifically, the instrument 130 is not such a scale mechanism. Huebner is completely silent as to the instrument 130 including any value that would enable the instrument 130 to function as a scale mechanism. Rather, the instrument 130 is used to adjust the height of the head and the retroversion of the implant (i.e., the rotational angle of the shaft within the humerus) without the use of any value on the instrument 130.

The Examiner refers to column 7, lines 36-54 of Huebner as disclosing a scale mechanism with a value. This passage of Huebner is directed to the use of reference marks 200 on the implant, as shown in Fig. 22. The marks 200 include gradations 206 which are used to mark the penetration depth of the shaft 16 into the humerus, and angular indications 204 which are used to mark the rotational angle of the shaft 16 within the humerus. Applicants respectfully point out that



the marks 200 are not on a scale mechanism in which the implant is positioned, as required by claim 53. Rather, the marks 200 are on the implant itself.

Moreover, Huebner does not disclose a trial offset indicia aligning with marks 200, as required by claim 53. As discussed above with respect to claim 49, the head 12 is not offset, and thus does not include any offset indicia that align with a value on a scale mechanism. Even the recess 108 that the Examiner refers to as an offset indicia does not align with any of the marks 200 on the implant. Thus, Huebner does not disclose or suggest positioning a trial assembly in a scale mechanism whereby a trial offset indicia of a trial head portion aligns with a value on the scale mechanism, as recited by claim 53.

Further, claim 53 recites in part the following:

securing a final head portion to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

Huebner not disclose or suggest securing a final head portion to a final body portion based on a value on a scale mechanism, as recited by claim 53. More particularly, Huebner does not disclose that the head 12 is secured to the body 18 based on any value on the instrument 130.

Huebner also does not disclose securing the head 12 to the body 18 based on the marks 200, as required by claim 53. Rather, use of the reference marks 200 facilitates installation and alignment of the implant into the humeral bone. Thus, Huebner does not disclose or suggest securing a final head portion

to a final body portion based on a value of a scale mechanism, as required by claim 53.

For all of the foregoing reasons, Huebner does not disclose or suggest Applicants' invention of claim 53. Thus, claim 53 is allowable over Huebner.

#### Discussion Re: Patentability of Claim 54

Claim 54 recites in part the following:

a trial head portion having (i) a trial head member which includes a trial offset indicia . . . ;

positioning said trial assembly in a scale mechanism . . . whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

attaching a final head portion in fixed relation to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

Thus, claim 54 recites subject matter substantially similar to the subject matter of claim 53. Moreover, claim 54 recites further novel and nonobvious limitations. As a result, claim 54 is allowable for the reasons hereinbefore discussed with regard to claim 53.

Discussion Re: Patentability of Claim 55

Claim 55 recites in part the following:

a trial assembly including a trial body portion . . . , and a trial head portion having (i) a trial head member which includes a trial offset indicia, . . . ; and

a final prosthesis assembly including a final body portion . . . , and a final head portion having (i) a final head member which includes a final offset indicia.

(Emphasis added).

Thus, claim 55 recites subject matter substantially similar to the subject matter of claim 49. As a result, claim 55 is allowable for the reasons hereinbefore discussed with regard to claim 49. Moreover, claim 55 recites further novel and nonobvious limitations. Thus, claim 55 is further allowable over the cited art.

35 U.S.C. § 103 Rejections

Claims 1-2, 5-9, 11-17, 20-23 and 25-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Farey. Reconsideration of claims 1-2, 5-9, 11-17, 20-23 and 25-27 is respectfully requested.

Discussion Re: Patentability of Claim 1

Claim 1 recites in part the following:

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

securing a final head portion to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

Thus, claim 1 recites subject matter substantially similar to the subject matter of claim 45. As a result, claim 1 is allowable for the reasons hereinbefore discussed with regard to claim 45. Moreover, claim 1 recites further novel and nonobvious limitations. Thus, claim 1 is further allowable over the cited art.

Discussion Re: Patentability of Claims 2, 5-9 and 11-16

Claims 2, 5-9 and 11-16 depend directly or indirectly from claim 1. As a result, claims 2, 5-9 and 11-16 are allowable for the reasons hereinbefore discussed with regard to claim 1. Moreover, claims 2, 5-9 and 11-16 recite further novel and nonobvious limitations. Thus, claims 2, 5-9 and 11-16 are further allowable over the cited art.

Discussion Re: Patentability of Claim 17

Claim 17 recites in part the following:

positioning said trial assembly in a scale mechanism . . . whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;  
attaching a final head portion in fixed relation to a final body portion based on said value so as to form a final prosthesis assembly.

(Emphasis added).

Thus, claim 17 recites subject matter substantially similar to the subject matter of claim 1. As a result, claim 17 is allowable for the reasons hereinbefore discussed with regard to claim 1. Moreover, claim 17 recites further novel and nonobvious limitations. Thus, claim 17 is further allowable over the cited art.

Discussion Re: Patentability of Claims 20-23 and 25-27

Claims 20-23 and 25-27 depend directly or indirectly from claim 17. As a result, claims 20-23 and 25-27 are allowable for the reasons hereinbefore discussed with regard to claim 17. Moreover, claims 20-23 and 25-27 recite further novel and nonobvious limitations. Thus, claims 20-23 and 25-27 are further allowable over the cited art.

Claims 3-4, 10, 18-19 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Farey in view of Kummer et al. Reconsideration of claims 3-4, 10, 18-19 and 24 is respectfully requested.

### Claim 3

Claim 3 recites in part the following:

said trial body portion includes a set of internal threads located within said trial bore,  
said trial head portion further includes an externally threaded fastener positioned within a passageway which extends through said trial head portion.

(Emphasis added).

Thus, claim 3 recites subject matter substantially similar to the subject matter of claim 31. As discussed above with regard to claim 31, Kummer does not disclose internal threads located within a bore and external threads on a fastener, as recited by claim 3.

As the Examiner acknowledges, Farey also does not disclose internal threads located within a bore and external threads on a fastener, as recited by claim 3. As a result, claim 3 is allowable over Farey in view of Kummer. Moreover, claim 3 recites further novel and nonobvious limitations. Thus, claim 3 is further allowable over the cited art.

### Discussion Re: Patentability of Claims 4 and 10

Claims 4 and 10 depend directly or indirectly from claim 1. As a result, claims 4 and 10 are allowable for the reasons hereinbefore discussed with regard to claim 1. Moreover, claims 4 and 10 recite further novel and nonobvious limitations. Thus, claims 4 and 10 are further allowable over the cited art.

Discussion Re: Patentability of Claim 18

Claim 18 recites in part the following:

said trial body portion includes a set of internal threads located within said trial bore,

said trial head portion further includes an externally threaded fastener positioned within a passageway which extends through said trial head portion.

(Emphasis added).

Thus, claim 18 recites subject matter substantially similar to the subject matter of claim 3. As a result, claim 18 is allowable for the reasons hereinbefore discussed with regard to claim 3. Moreover, claim 18 recites further novel and nonobvious limitations. Thus, claim 18 is further allowable over the cited art.

Discussion Re: Patentability of Claims 19 and 24

Claims 19 and 24 depend directly from claim 17. As a result, claims 19 and 24 are allowable for the reasons hereinbefore discussed with regard to claim 17. Moreover, claims 19 and 24 recite further novel and nonobvious limitations. Thus, claims 19 and 24 are further allowable over the cited art.

Claims 29-30 and 38-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kummer et al. in view of Farey. Reconsideration of claims 29-30 and 38-39 is respectfully requested.

Discussion Re: Patentability of Claims 29 and 30.

Claims 29 and 30 depend directly or indirectly from claim 28. As a result, claims 29 and 30 are allowable for the reasons hereinbefore discussed with regard to claim 28. Moreover, claims 29 and 30 recite further novel and nonobvious limitations. Thus, claims 29 and 30 are further allowable over the cited art.

Discussion Re: Patentability of Claims 38 and 39

Claims 38 and 39 depend directly or indirectly from claim 36. As a result, claims 38 and 39 are allowable for the reasons hereinbefore discussed with regard to claim 36. Moreover, claims 38 and 39 recite further novel and nonobvious limitations. Thus, claims 38 and 39 are further allowable over the cited art.

Claims 34 and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kummer et al. Reconsideration of claims 34 and 43 is respectfully requested.

Discussion Re: Patentability of Claim 34

Claim 34 depends directly from claim 28. As a result, claim 34 is allowable for the reasons hereinbefore discussed with regard to claim 28. Moreover, claim 34 recites further novel and nonobvious limitations. Thus, claim 34 is further allowable over the cited art.



Discussion Re: Patentability of Claim 43

Claim 43 depends indirectly from claim 36. As a result, claim 43 is allowable for the reasons hereinbefore discussed with regard to claim 36. Moreover, claim 43 recites further novel and nonobvious limitations. Thus, claim 43 is further allowable over the cited art.

Claim 56


Claim 56 has been added hereby to further protect the patentable subject matter of the present invention. Claim 56 recites further novel and nonobvious limitations. Thus, claim 56 is further allowable over the cited art.

Conclusion

In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited.

Respectfully submitted,

Maginot, Moore & Bowman

  
Keith J. Swedo  
Attorney for Applicants  
Registration. No. 43,176

January 24, 2003

Maginot, Moore & Bowman  
Bank One Tower  
111 Monument Circle, Suite 3000  
Indianapolis, Indiana 46204-5130  
Phone: (317) 638-2922  
Fax: (317) 638-2139

## **Attachment**

### **Version With Markings to Show Changes Made to Specification**

#### In the Specification

On page 11, lines 23-27, please delete the paragraph beginning with "Referring" and ending with "prosthesis", and substitute the following paragraph in its place:

--Referring to Figs. 17 and 18 the trial assembly is placed into the impaction stand 70 (in Fig. 17, the eccentric head is not present to illustrate how the [body] stem 22 fits in the impaction stand 70/channel 74). As seen in Fig. 18 the position of the notch 44 in the trial eccentric head 42 is noted (here at position 5) for transference or reproduction onto the final prosthesis.--

## **Version With Markings to Show Changes Made to Abstract**

### **In the Abstract**

Please delete the abstract and substitute the following abstract in its place:

--A kit and associated method is [disclosed] for implanting a prosthetic device in a resected bone such as a humerus. The kit includes a trial assembly including a trial body portion having a trial bore defined therein, and a trial head portion having (i) a [trail] trial head member which includes a trial offset indicia, and (ii) an eccentrically located trial stem extending from the trial head member, the trial head stem being configured to be received within the trial bore. The kit also includes a final prosthesis assembly including a final body portion having a final bore defined therein, and a final head portion having (i) a final head member which includes a final offset indicia, and (ii) an eccentrically located final head stem extending from the final head portion, the final head stem being configured to be received within the final bore.--

## Version With Markings to Show Changes Made to Claims

Please amend claims 1, 10-13, 17, 28, 45-48, 50 and 52-54 as follows:

1. (Amended) A [method of implanting a final prosthesis assembly in a resected bone] prosthesis implantation method, comprising the steps of:

positioning a trial assembly in [said] a resected bone, said trial assembly including a trial body portion having a trial bore defined therein, and a trial head portion having (i) a trial head member which includes a trial offset indicia, and (ii) an eccentrically located trial head stem extending from said trial head member, said trial head stem being configured to be received within said trial bore;

rotating said trial head portion relative to said trial body portion while said trial assembly is positioned in said resected bone so as to position said trial head portion relative to said trial body portion at an aligned orientation whereby said trial head portion covers a resected surface of said resected bone;

removing said trial assembly from said resected bone after said rotating step;

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

securing a final head portion to a final body portion based on said value so as to form [said] a final prosthesis assembly; and

implanting said final prosthesis assembly in said resected bone after said securing step.

10. (Amended) The method of claim 9, wherein:  
said final head stem possesses a male taper configuration,  
said final body portion has a final bore defined therein,  
said final bore possesses a female taper configuration, and  
said [attaching] securing step includes the step of advancing said final head stem into said final bore in a friction fit manner.

11. (Amended) The method of claim 9, wherein:  
said scale mechanism includes an indicia surface,  
said value is indicated on said indicia surface,  
said scale mechanism further includes a channel [define] defined therein,  
and  
said [attaching] securing step includes locating said final body portion within said channel.

12. (Amended) The method of claim 11, wherein said [attaching] securing step further includes locating said final head portion adjacent to said indicia surface.

13. (Amended) The method of claim 12, wherein said [attaching] securing step further includes positioning said final head portion relative to said final body portion at said aligned orientation.

17. (Amended) A [method of implanting a final prosthesis assembly in a resected bone] prosthesis implantation method, comprising the steps of:

providing a [trial] trial assembly which includes a trial body portion having a trial bore defined therein, and a trial head portion having (i) a trial head member which includes a trial offset indicia, and (ii) an eccentrically located trial head stem extending from said trial head member;

positioning said trial body portion in [said] a resected bone;

positioning said trial stem in said trial bore after said trial body positioning step;

moving said trial head portion in relation to said trial body portion after said trial stem positioning step so as to locate said trial head portion relative to said trial body portion at a user-selected orientation;

securing said trial head portion to said trial body portion at said user-selected orientation;

removing said trial assembly from said resected bone after said securing step;

positioning said trial assembly in a scale mechanism after said removing step whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

attaching a final head portion in fixed relation to a final body portion based on said value so as to form [said] a final prosthesis assembly; and

implanting said final prosthesis assembly in said resected bone after said attaching step.

28. (Amended) A kit, comprising:

a trial assembly including a trial body portion having a trial bore defined therein, and a trial head portion having (i) a [trial] trial head member which includes a trial offset indicia, and (ii) an eccentrically located trial stem extending from said trial head member, said trial head stem being configured to be received within said trial bore; and

a final prosthesis assembly including a final body portion having a final bore defined therein, and a final head portion having (i) a final head member which includes a final offset indicia, and (ii) an eccentrically located final head stem extending from said final head portion, said final head stem being configured to be received within said final bore.

45. (Amended) A [method of implanting a final prosthesis assembly in a resected bone] prosthesis implantation method, comprising the steps of:

positioning a trial assembly in [said] a resected bone, said trial assembly including a trial body portion having a trial body mating component, and a trial head portion having (i) a trial head member which includes a trial offset indicia, and (ii) an eccentrically located trial head mating component, said trial head mating component being configured to mate with said trial body mating component;

rotating said trial head portion relative to said trial body portion while said trial assembly is positioned in said resected bone so as to position said trial head portion relative to said trial body portion at an aligned orientation whereby said trial head portion covers a resected surface of said resected bone;

removing said trial assembly from said resected bone after said rotating step;

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

securing a final head portion to a final body portion based on said value so as to form [said] a final prosthesis assembly; and

implanting said final prosthesis assembly in said resected bone after said securing step.

46. (Amended) The method of claim 45, wherein said trial body mating component and said trial head mating component are each selected from the [following] group consisting of: a bore and a stem.



47. (Amended) A [method of implanting a final prosthesis assembly in a resected bone] prosthesis implantation method, comprising the steps of:

providing a trial assembly which includes a trial body portion having a trial body mating component, and a trial head portion having (i) a trial head member which includes a trial offset indicia, and (ii) an eccentrically located trial head mating component;

positioning said trial body portion in [said] a resected bone;

mating said trial body mating component with said trial head mating component after said trial body positioning step;

moving said trial head portion in relation to said trial body portion after said mating step so as to locate said trial head portion relative to said trial body portion at a user-selected orientation;

securing said trial head portion to said trial body portion at said user-selected orientation;

removing said trial assembly from said resected bone after said securing step;

positioning said trial assembly in a scale mechanism after said removing step whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

attaching a final head portion in fixed relation to a final body portion based on said value so as to form [said] a final prosthesis assembly; and

implanting said final prosthesis assembly in said resected bone after said attaching step.

48. (Amended) The method of claim 47, wherein said trial body mating component and said trial head mating component are each selected from the [following] group consisting of: a bore and a stem.

50. (Amended) The kit of claim 49, wherein:

said trial body mating component and said trial head mating component are each selected from the following group: a trial bore and a trial stem, and said final body mating component and said final head mating component are each selected from the [following] group consisting of: a final bore and a final stem.

52. (Amended) The kit of claim 51, wherein said final body mating component and said final head mating component are each selected from the [following] group consisting of: a bore and a stem.

53. (Amended) A [method of implanting a final prosthesis assembly in a resected bone] prosthesis implantation method, comprising the steps of:

positioning a trial assembly in [said] a resected bone, said trial assembly including a trial body portion having a trial body mating component, and a trial head portion having (i) a trial head member which includes a trial offset indicia, and (ii) a trial head mating component, said trial head mating component being configured to mate with said trial body mating component, and wherein at least one of the following two components is eccentrically located: said trial body mating component and said trial head mating component;

rotating said trial head portion relative to said trial body portion while said trial assembly is positioned in said resected bone so as to position said trial head portion relative to said trial body portion at an aligned orientation whereby said trial head portion covers a resected surface of said resected bone;

removing said trial assembly from said resected bone after said rotating step;

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

securing a final head portion to a final body portion based on said value so as to form [said] a final prosthesis assembly; and

implanting said final prosthesis assembly in said resected bone after said securing step.

54. (Amended) A [method of implanting a final prosthesis assembly in a resected bone] prosthesis implantation method, comprising the steps of:

providing a trial assembly which includes a trial body portion having a trial body mating component, and a trial head portion having (i) a trial head member which includes a trial offset indicia, and (ii) a trial head mating component, wherein at least one of the following two components is eccentrically located:

said trial body mating component and said trial head mating component;

positioning said trial body portion in [said] a resected bone;

mating said trial body mating component with said trial head mating component after said trial body positioning step;

moving said trial head portion in relation to said trial body portion after said mating step so as to locate said trial head portion relative to said trial body portion at a user-selected orientation;

securing said trial head portion to said trial body portion at said user-selected orientation;

removing said trial assembly from said resected bone after said securing step;

positioning said trial assembly in a scale mechanism after said removing step whereby said trial offset indicia of said trial head portion aligns with a value on said scale mechanism;

attaching a final head portion in fixed relation to a final body portion based on said value so as to form [said] a final prosthesis assembly; and

implanting said final prosthesis assembly in said resected bone after said attaching step.

Please add claim 56 as follows:

56. A prosthesis implantation method, comprising the steps of:

positioning a trial assembly in a resected bone, said trial assembly including a trial body portion having a trial body mating component, and a trial head portion having (i) a trial head member which includes a trial offset indicia, and (ii) an eccentrically located trial head mating component, said trial head mating component being configured to mate with said trial body mating component;

rotating said trial head portion relative to said trial body portion while said trial assembly is positioned in said resected bone so as to position said trial head portion relative to said trial body portion at an aligned orientation whereby said trial head portion covers a resected surface of said resected bone;

removing said trial assembly from said resected bone after said rotating step;

positioning said trial assembly in a scale mechanism whereby said trial offset indicia of said trial head portion aligns with one of a series of gradations located on said scale mechanism;

securing a final head portion to a final body portion based on said value so as to form a final prosthesis assembly; and

implanting said final prosthesis assembly in said resected bone after said securing step.